

## REMARKS

The Office Actions mailed July 17, 2005 and November 23, 2005 and references cited therein have been reviewed. Applicants have canceled claims 1-58 and added new claims 59-115. Applicants have also amended the specification to address an antecedent basis problem. Applicants submit that the amendments to the specification do not constitute new matter.

The Examiner indicated in the Office Action mailed November 23, 2005 that the Amendment filed on September 16, 2005 was not fully responsive. Applicants respectfully disagree. The Examiner asserted that the reply must present arguments pointing out the specific distinctions believed to render the claims patentable over the cited art of record. Applicants submit that the arguments under the subheadings "THE 102 REJECTION" and "THE 103 REJECTION" include detailed arguments regarding the patentability of the newly submitted claims. Applicants sincerely believe that the arguments for patentability of the new pending claims is a "*bona fide* attempt to advance the application" to allowance. Applicants also submit that all of the Examiner's rejections in the Office Action mailed July 17, 2005 were fully addressed in the Response filed on September 16, 2005.

The Examiner also asserted that Applicants must indicate where support for the amendments to the claims is found in the specification. Applicants have reviewed MPEP 714.03 and 2163.06 and 37 C.F.R. §1.111 and could not locate the quote or passage set forth by the Examiner in these cited sections. MPEP 2163.06 is a section that only applies to the written description of the invention, not the amended claims. If the Examiner is unable to find support for the newly amended claims in the originally filed specification, the appropriate rejection appears to be a Section 112 rejection. Although Applicants believe that there is no statutory requirement or PTO rule to identify sections of the specification that support newly submitted claims, Applicants have provided that following

paragraph sections which support new independent claim 59, namely paragraphs 0001, 0002, 0022, 0025, 0031-0038, 0061, 0062, and 0064 as set forth in US Pub. 2005/0165476.

Applicants did amend the specification to include the language of original claims 39 and 40. Since the originally filed claims are part of the original specification, the addition of language from original claims 39 and 40 to the specification does not constitute new matter.

### **OBJECTIONS TO CLAIMS AND SPECIFICATION**

Claim 41 was objected to for not including the proper punctuation. Applicants have canceled claim 41 thereby making the objection moot.

The specification was objected to for not providing proper antecedent basis for the limitations in original claims 39 and 40. Claims 39 and 40 have been canceled, thereby making this rejection moot. Irrespective of this fact, the paragraph in the specification beginning at page 7, line 18 has been amended to provide proper antecedent basis for former original claims 39 and 40. Specifically, the text of original claims 39 and 40 have been added to the paragraph in the specification beginning at page 7, line 18. Applicants submit that the amendments to the specification do not constitute new matter.

### **THE SECTION 112(1) REJECTION**

The examiner objected to claims 39 and 40 under 35 U.S.C. §112(1) for not being described in the specification to enable one skilled in the art to make or use the invention. Although claims 39 and 40 have been canceled by this Amendment, thereby making the rejection moot, Applicants disagree with this rejection of the claims. United States Patent Publication Nos. 2004/0093076 and 2004/0093077 disclose stents that are formed by a microelectromechanical machining process that is used to form the teeth or other indentations that are part of the ratcheting mechanism. As such, Applicants submit that one skilled in the art of manufacturing stents would understand how, at the

time the present application was filed, to form a stent by a microelectromechanical machining process and to use such process to form the teeth or other indentations that are part of the ratcheting mechanism.

### **THE SECTION 102 REJECTION**

Claims 1, 2, 4, 5, 8, 9, 12, 13, 15, 16, 19-23, 31, 32, 36, 37, 41, 42, 44, 47-49, 52, 54 and 56 were rejected under 35 U.S.C. §102(b) as being anticipated by Reich. Applicants have canceled these claims thereby making the rejection moot.

Applicants submit that the new independent claims are not anticipated by Reich. All the new pending claims include the limitations that the graft 1) includes a first drug layer at least partially coated on the wall of the graft, 2) the graft includes an inner layer formed of a porous material designed to promote endothelialization, 3) the first drug layer includes at least one drug and a flexible and substantially biologically inert amphiphilic block copolymer, 4) the amphiphilic block copolymer has a structure that controllably releases up to about 90 percent of at least one of the drugs within about thirty days of the graft being connected to or inserted into the blood vessel, and 5) at least one drug in the first drug layer is formulated to inhibit stenosis, vascular narrowing and/or thrombosis. Applicants submit that Reich does not disclose, teach or suggest claim elements 2, 4 and 5 in the new pending claims. Furthermore, Reich does not disclose, teach or suggest this combination of the five claim elements of the new pending claims. For at least these reasons, the new independent claims and all the claims dependent therefrom are not anticipated or made obvious by Reich.

### **THE SECTION 103 REJECTION**

Claims 6, 7, 10, 11, 27, 29, 30, 43, 45, 46, 50, 51, 53, 55, 57, and 58 were rejected under 35 U.S.C. 103(a) as being unpatentable over Reich in view of Furst and Hammond. Applicants have

canceled these claims thereby making the rejection moot.

Applicants submit that these three references do not disclose, teach or suggest all of the limitations of the new pending independent claims. As stated above, all the new pending claims include the limitations that the graft 1) includes a first drug layer at least partially coated on the wall of the graft, 2) the graft includes an inner layer formed of a porous material designed to promote endothelialization, 3) the first drug layer includes at least one drug and a flexible and substantially biologically inert amphiphilic block copolymer, 4) the amphiphilic block copolymer has a structure that controllably releases up to about 90 percent of at least one of the drugs within about thirty days of the graft being connected to or inserted into the blood vessel, and 5) at least one drug in the first drug layer is formulated to inhibit stenosis, vascular narrowing and/or thrombosis. Applicants submit that Reich, Furst and Hammond do not disclose, teach or suggest claim elements 2 and 4 of the new pending claims. Furthermore, Reich, Furst and Hammond do not disclose, teach or suggest this combination of the five claim elements of the new pending claims. For at least these reasons, the new independent claims and all the claims dependent therefrom are not made obvious by Reich, Furst and Hammond.

Claim 14 was rejected under 35 U.S.C. 103(a) as being unpatentable over Reich in view of Roorda. Applicants have canceled claim 14 thereby making the rejection moot.

Applicants submit that these two references do not disclose, teach or suggest all of the limitations of the new pending independent claims. As stated above, all the new pending claims include the limitations that the graft 1) includes a first drug layer at least partially coated on the wall of the graft, 2) the graft includes an inner layer formed of a porous material designed to promote endothelialization, 3) the first drug layer includes at least one drug and a flexible and substantially biologically inert amphiphilic block copolymer, 4) the amphiphilic block copolymer has a structure

that controllably releases up to about 90 percent of at least one of the drugs within about thirty days of the graft being connected to or inserted into the blood vessel, and 5) at least one drug in the first drug layer is formulated to inhibit stenosis, vascular narrowing and/or thrombosis. Applicants submit that Reich and Roorda do not disclose, teach or suggest claim elements 2, 4 and 5 of the new pending claims. Furthermore, Reich and Roorda do not disclose, teach or suggest this combination of the five claim elements of the new pending claims. For at least these reasons, the new independent claims and all the claims dependent therefrom are not made obvious by Reich and Roorda.

Claims 2, 3, 17-19, 24-28 and 53 were rejected under 35 U.S.C. 103(a) as being unpatentable over Reich in view of Brauker. Applicants have canceled claims 2, 3, 17-19, 24-28 and 53 thereby making the rejection of these claims moot.

Applicants submit that these two references do not disclose, teach or suggest all of the limitations of the new pending independent claims. As stated above, all the new pending claims include the limitations that the graft 1) includes a first drug layer at least partially coated on the wall of the graft, 2) the graft includes an inner layer formed of a porous material designed to promote endothelialization, 3) the first drug layer includes at least one drug and a flexible and substantially biologically inert amphiphilic block copolymer, 4) the amphiphilic block copolymer has a structure that controllably releases up to about 90 percent of at least one of the drugs within about thirty days of the graft being connected to or inserted into the blood vessel, and 5) at least one drug in the first drug layer is formulated to inhibit stenosis, vascular narrowing and/or thrombosis. Applicants submit that Reich and Brauker do not disclose, teach or suggest claim elements 2, 4 and 5 of the new pending claims. Furthermore, Reich and Brauker do not disclose, teach or suggest this combination of the five claim elements of the new pending claims. For at least these reasons, the new

independent claims and all the claims dependent therefrom are not made obvious by Reich and Brauker.

Claims 32-35 were rejected under 35 U.S.C. 103(a) as being unpatentable over Reich in view of Kennedy. Applicants have canceled claims 32-35 thereby making the rejection of these claims moot.

Applicants submit that these two references do not disclose, teach or suggest all of the limitations of the new pending independent claims. As stated above, all the new pending claims include the limitations that the graft 1) includes a first drug layer at least partially coated on the wall of the graft, 2) the graft includes an inner layer formed of a porous material designed to promote endothelialization, 3) the first drug layer includes at least one drug and a flexible and substantially biologically inert amphiphilic block copolymer, 4) the amphiphilic block copolymer has a structure that controllably releases up to about 90 percent of at least one of the drugs within about thirty days of the graft being connected to or inserted into the blood vessel, and 5) at least one drug in the first drug layer is formulated to inhibit stenosis, vascular narrowing and/or thrombosis. Applicants submit that Reich and Kennedy do not disclose, teach or suggest claim elements 2, 4 and 5 of the new pending claims. Furthermore, Reich and Kennedy do not disclose, teach or suggest this combination of the five claim elements of the new pending claims. For at least these reasons, the new independent claims and all the claims dependent therefrom are not made obvious by Reich and Kennedy.

Claims 38-40 were rejected under 35 U.S.C. 103(a) as being unpatentable over Reich in view of McGuinness. Applicants have canceled claims 38-40 thereby making the rejection of these claims moot.

Applicants submit that these two references do not disclose, teach or suggest all of the

limitations of the new pending independent claims. As stated above, all the new pending claims include the limitations that the graft 1) includes a first drug layer at least partially coated on the wall of the graft, 2) the graft includes an inner layer formed of a porous material designed to promote endothelialization, 3) the first drug layer includes at least one drug and a flexible and substantially biologically inert amphiphilic block copolymer, 4) the amphiphilic block copolymer has a structure that controllably releases up to about 90 percent of at least one of the drugs within about thirty days of the graft being connected to or inserted into the blood vessel, and 5) at least one drug in the first drug layer is formulated to inhibit stenosis, vascular narrowing and/or thrombosis. Applicants submit that Reich and McGuinness do not disclose, teach or suggest claim elements 2, 4 and 5 of the new pending claims. Furthermore, Reich and McGuinness do not disclose, teach or suggest this combination of the five claim elements of the new pending claims. For at least these reasons, the new independent claims and all the claims dependent therefrom are not made obvious by Reich and McGuinness.

Applicants further submit that in addition to the fact that none of the cited references disclose, teach or suggest the limitations of the new pending independent claims, several of the pending dependent claims also include limitations that are not disclosed, taught or suggested by the cited art of record. Non-limiting examples of such dependent claims include claims 61-75, 78-92 and 96-115.



Applicants submit that all the new pending claims are in condition for allowance.

Respectfully submitted,  
FAY, SHARPE, FAGAN, MINNICH & McKEE

By: 

BRIAN E. TURUNG

Reg. No. 35,294

1100 Superior Avenue, Seventh Floor

Cleveland, Ohio 44114-2579

Telephone: (216) 861-5582

Facsimile: (216) 241-1666

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